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CLARK, GREGORY D	

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1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,123	PASBRIG, ERWIN	
	Examiner	Art Unit	
	GREGORY CLARK	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the receipt of the Applicant's Amendment, received 02/05/2009. Claims 1-30 pending; 1, 10 and 24 currently amended; 2-9, 11-23, and 25- 30 previously presented.

Rejections and objections made in the previous office action that does not appear below have been overcome by applicant's amendments and therefore the arguments pertaining to these rejections/objections will not be addressed.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claim 1-3, 10-13, 20, 24-26 are rejected under 35 U.S.C. 103(a) unpatentable over Bunin (4,911,304) and Klein (2004/0103716).**

3. **Regarding Claims 1, 3, 10, 13, 20 and 26,** Bunin teaches a blister pack for tablets or similar article characterized by a 20 to 25 micron thick aluminum film (Column

2, line 33) which is uncoated one side and laminated with a layer of 0.02-0.025 millimeters (20-25 microns) thick polyvinyl chloride (PVC, cover) (Column 2, lines 38 and 39) on the other side. Bunin discloses that a heat-formable process (thermoformed) is used to make the blister package (column 2, lines 18-20). Buin also discloses that the coated aluminum foil design imparts the desired moisture/vapor/gas barrier protection (column 1, 28-33).

The applicant claims an aluminum thickness of 5 to 50 microns (per claim 1) and 7 to 30 microns (per claims 13, 20 and 26).

There is substantial overlap between the thickness value for aluminum disclosed by Bunin and the applicant.

Bunin and the claims differ in that Bunin does not teach the exact same proportions as recited in the instant claims. However, one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the thickness proportions taught by Bunin overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

> "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

The applicant claims the other side of the aluminum foil is laminated with polychlorotrifluoroethylene (PCTFE) with a film thickness of 8 to 76 microns.

Buin discloses that the plastic materials that can be used for the plastic film portion of the blister package are resilient, heat formable and heat sealable such as polyvinyl chloride (PVC), polyvinylidine chloride, and fluoro plastics (column 2, line 18-22). Buin does not specifically mention PCTFE as a plastic material in a blister pack.

Klein discloses a blister pack containing an aluminum foil composite structure where a plastic film is bonded to the aluminum foil (paragraph 46). Suitable materials for the plastic films include PVC (polyvinylchloride), COC (cycloolefin-copolymer), polychlorotrifluoroethylene, polyethylene, polypropylene, polyethylene terephthalate, polycarbonates, polyesters, polyacrylates, polyamides or other plastics (paragraph 47). Klein gives a thickness range of 10 to 40 microns for the polyamide layer covering the aluminum layer (paragraph 83). As polyamide is listed as one of the plastic materials that can be bonded to the aluminum layer, any material listed in the group presented by Klein is viewed a suitable substitutes that could be used within the same thickness range, including polychlorotrifluoroethylene.

There is substantial overlap between the thickness claimed by the applicant and the thickness range of Klein.

Klein and the claimed invention differs in that Klein does not teach the exact same proportions as recited in the instant claims.

However, one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Klein overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

> "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Klein also teaches that the foil containers (blister pack) are used to protect the pharmaceutical formulations from external environmental influences which include moisture (paragraph3).

The list of suitable plastic materials disclosed by Buin includes PVC and fluoro plastics. The list of suitable plastic materials disclosed by Klein includes PVC and polychlorotrifluoroethylene (PCTFE). The plastic materials disclosed by Buin and Klein

are bonded to the aluminum foil component of a blister pack and have the same general properties, namely moisture vapor barrier films.

With a reasonable expectation of success, a person of ordinary skill in the art would select a plastic polymer with known moisture vapor barrier properties such as those disclosed by Buin and Klein that includes PCTFE, claimed by the applicant. Buin discloses the claimed invention except for polychlorotrifluoroethylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select from all plastic materials with known moisture barrier properties such as those taught by Klein (namely, PCTFE), since it has been held to be within general skill of a worker in the art to select a known material (in this case with known moisture vapor barrier properties) on the basis of its suitability for the intended use as a matter of obvious design choice.

4. **Regarding Claim 24**, Bunin and Klein disclose a blister package where the aluminum foil is coated on one side with polychlorotrifluoroethylene as discussed above.

Bunin discloses a lamination process can be used to make the blister packs (abstract) but fail to mention an extrusion method. Klein discloses that the process to make such blister packs includes the coextrusion method (paragraph 54).

The examiner takes the position that the process to make blister packs was well known in the art at the time of the invention. The process by which a blister pack is made represents a process limitation which is therefor not considered as patentable subject matter.

If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (In re Thorpe, 227 USPQ 964,966). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evident establishing an unobvious difference between the claimed product and the prior art product (in re Marosi, 710 F.2nd, 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113).

5. **Regarding Claims 2, 12, 25**, Bunin does not the aluminum film is in a soft or hard state or has a defined hardness. Bunin discloses that the thickness of the aluminum film is such that it enables the pills or tablets to be removed by manually pushing them through and rupturing the cover sheet (column 1, lines 52-55).

The examiner takes the position that Bunin defines the factors that determine the softness or hardness of the aluminum film. The aluminum film must be soft enough to allow pills or tablets to be removed by manually pushing and the aluminum film must be soft enough to prevent the pills or tablets from rupturing the cover sheet prematurely.

With a reasonable expectation of success, at the time of the invention a person of ordinary skill in the art would adjust the softness and hardness of the aluminum film to achieve the desired balance. In the process of routine experimentation to determine this balance the soft or hard state would be of a defined hardness which read on the instant claim, absent unexpected results.

6. **Regarding Claim 11**, Bunin and Klein do not teach the blister base on to which is sealed the cover film contains the same material as the plastic film which is sealed to the blister base part.

The examiner takes the position that a skilled artisan with a reasonable expectation of success would ensure that the side of the blister base which is sealed to the cover film contained a material which had good compatibility with polychlorotrifluoroethylene such as non-polar coating resins or polychlorotrifluoroethylene itself. The purpose would be to ensure that there was good interfacial adhesion in order to produce a good seal between the two surfaces which would be less likely to allow moisture to enter the enclosed cavity. The compatibility of the two surfaces would be taken into due consideration and it would have been obvious at the time of the invention to a person of ordinary skill in the art to make such routine determinations to ensure good interfacial adhesion.

7. **Claims 4-9, 14-19, 21-23 and 27-30, are rejected under 35 U.S.C. 103(a) unpatentable over Bunin (4,911,304) and Klein (2004/0103716) in view of Ludemann (6,006,913).**

8. **Regarding Claim 4**, Bunin and Klein teach a blister pack but fail to teach a protective lacquer bonded to the aluminum foil. Ludemann teaches a blister pack

characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) (Column 3, lines 61-66).

Ludemann fails to mention whether the polyester is delivered from a watery or organic solvent.

With a reasonable expectation of good results, a person of ordinary skill in the art at the time of the invention through routine experimentation would determine the appropriate liquid medium to deliver the coating which would include watery or organic solvent based option that reads on the instant claim.

It would have been obvious to some one of ordinary skill in the art at the time of the invention to combine the protective layer of Ludemann with the unprotected aluminum foil taught by Bunin and Klein since Ludemann indicates that the issues related to low puncture resistance of the aluminum is decreased by the protective layer (Column 4, lines 45-47).

9. **Regarding Claim 9**, Bunin and Klein do not teach a blister pack comprising aluminum bonded to a protect lacquer layer. Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) which includes PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61-66). Ludemann does not mention how the protective lacquer layer is bonded to the aluminum foil. Ludemann teaches that the protective layer ensures a permanent connection between the aluminum foil (push-through layer) and the packaging lower

part (Column 3, lines 4-6). Ludemann also teaches that the layers can be formed by coextrusion (column 4, line 55-56).

It would have been obvious to some one of ordinary skill in the art at the time of the invention to combine the protective layer of Ludemann with the unprotected aluminum foil taught by Bunin and Klein since Ludemann indicates that issue related to low puncture resistance of the aluminum is decreased by the protective layer (Column 4, lines 45-47).

10. **Regarding Claim 14,** Bunin and Klein disclose a blister package where the aluminum foil outer cover layer is not protected with protective lacquer.

Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) which includes PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61-66). Ludemann teaches that the protective layer ensures a permanent connection between the aluminum foil (push-through layer) and the packaging lower part (Column 3, lines 4-6).

It would have been obvious to some one of ordinary skill in the art at the time of the invention to combine modify the uncoated aluminum foil cover of Bunin/Klien with the protective layer of Ludemann since Ludemann indicates that the low puncture resistance of the aluminum is decreased by the protective layer (Column 4, lines 45-47).

11. **Regarding Claims 5 and 15,** Bunin/Klein and Ludemann disclose a protective lacquer applied to the aluminum foil but fail to teach a coating weight of 0.5 to 5 g/m^2 as claimed by the applicant.

With a reasonable expectation of success, a person of ordinary skill in the art with the teaching of Bunin/Klein and Ludemann would through routine experimentation determine the appropriate coating weight of the protective lacquer to ensure adequate prevention of the low puncture tendency of unprotected aluminum. Such determinations would cover a range of coating weights including the 0.5 to 5 g/m^2 claimed by the applicant, absent unexpected results.

12. **Regarding Claim 27,** Bunin/Klein fail to teach a protective lacquer layer. Ludemann disclose a protective lacquer made from a polyester resin (Column 3, lines 61-66). Ludemann fails to mention whether the polyester is delivered from a watery or organic solvent.

With a reasonable expectation of good results, a person of ordinary skill in the art at the time of the invention through routine experimentation would determine the appropriate medium to deliver the coating which would include watery or organic solvent based options that read on the instant claim.

13. **Regarding Claims 16, 22 and 28,** Bunin and Klein do not teach a blister package where there is a paper layer on the side the aluminum foil.

Ludemann teaches a blister pack where a paper pull-off layer is on the side of the aluminum foil. Ludemann further teaches that the paper layer is often reinforced with plastic (coated paper) (column 1, lines 50-55).

Although Ludemann does not mention all the types of paper claimed by the applicant, a skilled artisan would select from a variety of different paper substrate which would include all the paper types claimed by the applicant.

14. **Regarding Claims 7 and 17,** Bunin and Klein do not teach a blister package where there is a paper layer on the side the aluminum foil.

Ludemann teaches a blister pack where a paper pull-off layer is in the side of the aluminum foil. Ludemann further teaches that the paper layer is often reinforced with plastic (coated paper) (column 1, lines 50-55). Ludemann fails to mention a paper substance weight of 19 to 50 g/m^2 as claimed by the applicant.

With a reasonable expectation of success, a person of ordinary skill in the art with the teaching of Bunin/Klein and Ludemann would through routine experimentation determine the appropriate coating paper substance weight to ensure adequate prevention aluminum foil. Such determinations would cover a range of coating weight including the 19 to 50 g/m^2 claimed by the applicant.

15. **Regarding Claims 8, 18-19, 23 and 29,** Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) which includes polyester and

PVC (plastic) (Column 3, lines 61-66). Ludemann does not teach that the polyester or PVC is pasted to the aluminum foil with a watery, a solvent-based or solvent-free adhesive. Ludemann also teaches that the layers can be formed by coextrusion (column 4, line 55-56).

The portion of claims which requires "pasted" is considered to be a product by process limitation and if not given patentable weight. "Even though product-by-process claims are limited by and defined by the process, determination of the patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (In re Thorpe, 227 USPQ 964,966). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evident establishing an unobvious difference between the claimed product and the prior art product (in re Marosi, 710 F.2nd, 802, 218 USPQ 289, 292 (Fed. Cir. 1983, MPEP 2113).

The examiner takes the position that a person of ordinary skills in the art at the time of the invention would apply the polyester layer or the PVC layer to the adhesive treated aluminum foil by any one of commonly used coating methods which would include a watery, a solvent-based or a solvent-free delivery method as claimed by the applicant.

16. **Regarding Claim 30,** Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (sealing layer) which includes polyester (Column 3, lines 61-66). Ludemann also teaches that the layers cab be formed by coextrusion (column 4, line 55-56).

17. **Regarding Claim 21,** Bunin and Klein disclose a blister package where the aluminum foil outer cover layer is not protected with protective lacquer.

Ludemann teaches a blister pack characterized by aluminum foil (push-through layer, Column 1, line 55) which on one side has been bonded to a protective layer (lacquer or sealing layer) which includes PVC, polystyrene, styrene copolymers, polyester, and polyolefins (Column 3, lines 61-66). Ludemann teaches that the protective layer ensures a permanent connection between the aluminum foil (push-through layer) and the packaging lower part (Column 3, lines 4-6). Ludemann dose not teach the protective lacquer is based on watery or organic solvents on the basis of nitrocellulose.

The examiner takes the position the instant " the lacquer is based on watery or organic solvents on the basis of nitrocellulose" is a process limitation and is therefor not patentable subject matter.

At the time of the invention a person of ordinary skill in the art would selected the appropriate lacquer either water based or organic solvent based and through routine

experimentation determine the appropriate medium of delivery which would include material such as nitrocellulose.

18. **Regarding Claims 6,** Bunin and Klein do not teach a blister pack that comprises an aluminum foil which on one side is bonded to a paper layer.

Ludemann teaches a blister pack where a paper pull-off layer is on the side of the aluminum foil. Ludemann further teaches that the paper layer is often reinforced with plastic (coated paper) (column 1, lines 50-55).

Although Ludemann does not mention all the types of paper claimed by the applicant, a skilled artisan would select from a variety of different paper substrate which would include all the paper types claimed by the applicant.

Response to Amendment

The examiner has considered the applicants' arguments but they are considered moot with the new round of rejections in the current office active. The prior art clearly discloses a blister pack with an aluminum foil component bonded to various substrates including paper(s) and plastic(s). The examiner treated the original claims limitations in the first office action, but amendments to claims 1, 10 and 24 which now focuses on polychlorotrifluoroethylene necessitated the new ground(s) of rejections presented in this Office action. The basic structure of the blister pack is disclosed in the prior art and the softness/hardness of the aluminum foil, the type of paper boned to the aluminum

foil, and the weight of a given layer are considered as aspects of the creative process that a skilled artisan would appropriately select and optimize accordingly which is deemed to read on the applicants' claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY CLARK whose telephone number is (571)270-7087. The examiner can normally be reached on M-Th 7:00 AM to 5 PM Alternating Fri 7:30 AM to 4 PM and Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1794

GREGORY CLARK /GDC/
Examiner
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